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|-----------------------------|-----------------|----------------------|---------------------|------------------|
| 10/038,168 | 10/23/2001 | Gregory L. Heacock | 12726US02 | 7813 |
| 7590 07/11/2006 | | | EXAMINER | |
| McANDREW | S, HELD & MALLO | WERNER, BRIAN P | | |
| 34th Floor 500 W. Madiso | n Street | ART UNIT | PAPER NUMBER | |
| Chicago, IL 60661 | | | 2624 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | | |
|---|---|---|--|---------------------|--|--|--|--|
| Office Action Summary | | 10/038,168 | HEACOCK, GRE | HEACOCK, GREGORY L. | | | | |
| | | Examiner | Art Unit | | | | | |
| | | Brian P. Werner | 2621 | | | | | |
| The MAILING DATE of Period for Reply | of this communication app | ears on the cover shee | et with the correspondence a | iddress | | | | |
| A SHORTENED STATUTO WHICHEVER IS LONGER, - Extensions of time may be available after SIX (6) MONTHS from the mail - If NO period for reply is specified ab Failure to reply within the set or exte Any reply received by the Office late earned patent term adjustment. See | FROM THE MAILING DA under the provisions of 37 CFR 1.13 ing date of this communication. ove, the maximum statutory period we nded period for reply will, by statute, r than three months after the mailing | ATE OF THIS COMMU 16(a). In no event, however, ma till apply and will expire SIX (6) cause the application to become | JNICATION. ay a repty be timely filed MONTHS from the mailing date of this he ABANDONED (35 U.S.C. § 133). | • | | | | |
| Status | | | | | | | | |
| 1) Responsive to comm | unication(s) filed on 19 Ju | <u>ne 2006</u> . | | | | | | |
| 2a) ☐ This action is FINAL. | | action is non-final. | | | | | | |
| 3) Since this application | is in condition for allowar | on for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | | |
| Disposition of Claims | | | | | | | | |
| 4)⊠ Claim(s) <u>1-39</u> is/are p | ending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | | |
| 5)⊠ Claim(s) <u>30-39</u> is/are allowed. | | | | | | | | |
| 6)⊠ Claim(s) <u>1-3,5-17,19-23 and 25-29</u> is/are rejected. | | | | | | | | |
| 7)⊠ Claim(s) <u>4, 18, 24</u> is/a | 7)⊠ Claim(s) <u>4, 18, 24</u> is/are objected to. | | | | | | | |
| 8) Claim(s) are so | ubject to restriction and/or | election requirement. | | | | | | |
| Application Papers | | | | | | | | |
| 9) The specification is ob | jected to by the Examiner | | | | | | | |
| 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. | | | | | | | | |
| Applicant may not reque | est that any objection to the o | Irawing(s) be held in abe | eyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | | |
| 12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)☐ All b)☐ Some * c)☐ None of: | | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | | |
| application from | the International Bureau | (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| | | | | | | | | |
| Attachment(s) | | | | | | | | |
| 1) Notice of References Cited (PTO | -892) | | ew Summary (PTO-413) | | | | | |
| Notice of Draftsperson's Patent D Information Disclosure Statemen | | | (s)/Mail Date Informal Patent Application (PTO-152) | | | | | |
| Paper No(s)/Mail Date | · · · · · · · · · · · · · · · · · · · | 6) Other: | | • | | | | |

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DETAILED ACTION

Response to Amendment

- 1. Applicant's after final amendment received on June 19, 2006 has been entered. The amendment serves to overcome the previous 112 rejections of claims 1-29. Claims 1-39 are currently pending, of which claims 30-39 remain allowable. Claims 1-29 are now rejected over the prior art.
- 2. Finality is withdrawn in view of claim elements taught by Rice et al. (US 6,305,804 B1) not previously relied upon by the examiner, and in view of Hill (US 4,393,366 A), both of whom teach the previously claimed and currently amended "alignment" limitations as described herein below.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1, 8, 9, 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rice et al. (US 6,305,804 B1), Hill (US 4,393,366 A used herein as an inherency teaching only) and Kim et al. (US 6,594,377 B1).

Regarding claim 1, Rice discloses a system for capturing an image of a retina of an eye (figures 1, 3 and 4) for identification (not afforded patentable weight: this is an intended use limitation, not referred back to in the claim body, and not necessary to give life and meaning to the claim) comprising:

a source of illumination light (figure 1, numeral 12);

a lens through which the illumination light passes to illuminate the retina, the lens receiving light reflected from the retina (figure 1, numeral 11; "lenses for projecting illumination light onto the fundus ... and for receiving the light reflected from the fundus" at column 4, line 22);

an image signal generator responsive to light reflected from the retina to generate a signal representing an image of an illuminated area of the retina (figure 1, numeral 22; "the light is reflected from the fundus of the eye 10 ... entering, e.g., a charge coupled device (CCD) detector 22" at column 4, line 47); and

an alignment system to align the eye along an axis that is at a predetermined angle with respect to a centerline of the lens, the angle being selected such that when the eye is aligned along said axis, said centerline intersects an area of the retina other than the fovea (

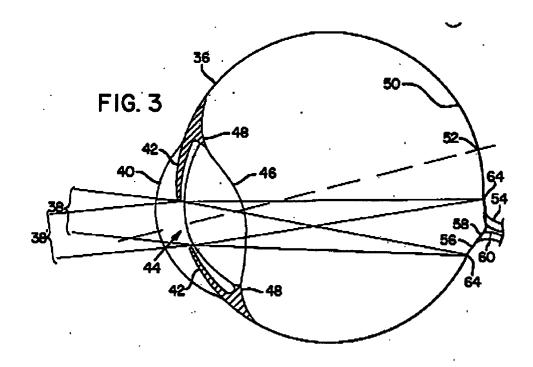
As described below, Rice teaches a target that is viewed by the fovea whereby an image of the optic disk (which is an area of the eye other than the fovea) is aligned with a centerline of a lens and CCD camera as follows:

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"A coaxial "scene" or visual light target may be included in the visual field of the device so that a patient can fixate his or her eye on this scene" where the "location of this visual target will bring the optic disk into the approximate center of the CCD detector" at column 4, lines 58-64; Light in the "visible or infrared range is projected into the eye onto the fundus", and the light reflected back out (e.g., through the pupil) is detected and analyzed, preferably using the area of the optic disk for analyzing the retinal vessels overlaying the optic disk" at column 1, lines 59-65. "measurement of the reflected light from the vessels overlaying the optic disk is preferred" at column 2, line 39

The "fovea" of an eye is the area of sharpest vision. The "optic disk" of an eye is the area where the optic nerve enters the eye, and where there is no vision at all (i.e., the "blind spot"). The fovea and optic disk are separated by an angle of approximately 14 degrees, which is depicted by Figure 3 of the Hill reference, reproduced below, by numerals 52 (fovea) and 56 (optic disk). The Rice system seeks to capture an image of the "optic disk", whereby a visual target is provide to the user which when viewed (i.e., focused on the fovea), projects the optic disk image onto the center of the CCD camera. The CCD camera is centered with the lens as depicted in Rice's figure 1, and as is well known in the art. Thus, given that when the user views the target, the optic disk is centered with the lens and CCD, the target must necessarily be positioned at a predetermined angle with respect to the center of the lens. This is depicted by the Hill reference, as figure 3, as follows:

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In Hill's figure 3, numeral 38' represents a "centering beam" that a user views and which is focused on the fovea 52 as depicted by the dashed centerline. Numeral 38 represents the scanning beam that scans the optic disk 56. It is clear that there is an angle between the centerline of the scanning beam and the centerline of the centering beam.

);

While Rice discloses an alignment system for ensuring that an adequate focus is achieved ("focus system 16 ... automatically find and bring the optic disk into focus" at column 5, line 22;

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"a motor drive system that slightly gimbals the lens system" at column 5, line 38 – thus, the lens system is moved to bring the retina into focus),

Rice does not disclose an ultrasonic transducer, the system being responsive to the transducer to determine when the eye is a predetermined distance from the image capture device and providing an indication to the user when the eye is at the predetermined distance.

Kim discloses a system for photographing an eye (figures 2-4), comprising an ultrasonic distance transducer ("the distance detector 18 measures a distance by using the infrared light. However, a detector using an ultrasonic wave may be employed" at column 3, line 59), the system being responsive to the transducer to determine when the eye is a predetermined distance from the image capture device ("the distance detector 18 measures a distance between the user and the optical imager, and transmits the measured distance value to the controller 200 through the optical imager driving unit 24. The control unit 200 judges whether the eye of the user is positioned within a predetermined operational range" at column 4, line 33) and providing an indication to the user when the eye is at the predetermined distance ("When it is judged that the user is positioned within the operational range, the control unit 200 outputs the control signal to the optical imager 100, thereby automatically enabling the optical imager 100. That is, the camera 10 prepares for capturing the iris image of the user, and simultaneously optical imager driving unit 24 outputs to the outside indicator 22 an active signal informing that the optical imager 100 is enabled" at column 4, line 35).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to incorporate the distance detector of Kim, into the system disclosed by Rice, to judge

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when the user is in the "operational range" (Kim, column 4, line 33), and then to activate the detector for capturing the image and to output an outside "signal informing that the optical imager 100 is enabled" (Kim, column 4, line 41). One would be motivated to do so by the following factors:

To inform the user of immanent image capture and to therefore remain still;

To properly and accurately adjust the focus mechanism based on the exact distance determined as described by Kim at column 4, line 53 through column 5, line 5 (see "The control unit 200 receives the distance value, computes a zoom-in/zoom-out value and a focus value by using a property table of the camera according to a value corresponding to the distance value, and controls a zoom motor and a focus motor of the camera according to the computed value" and "decides a zoom magnification from the zoom magnification table of the camera according to the previously-set distance by using the distance value between the camera and the iris, transmits the control signal to the camera, and controls the zoom motor of the camera.

Accordingly, the zoom lens is directly moved, the focus lens is moved to a corresponding position by controlling the focus motor, and thus the focus is directly controlled"), and to increase the focusing speed ("the focusing speed is increased" at Kim, column 5, line 5).

Regarding claims 8 and 9, Kim's indicator is visual and audible ("an outside indicator 22 indicating a result with predetermined lamps" at column 3, line 10; "an outside indicator 22/speaker 20-2" at column 3, line 45).

Regarding claim 10, Rice's illumination is non-scanned (e.g. "xenon strobe ... halogen source" at column 4, line 45).

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Regarding claim 14, Rice discloses a CCD camera (figure 1, numeral 22).

5. Claims 2, 3, 5, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rice et al. (US 6,305,804 B1), Hill (US 4,393,366 A – used herein as an inherency teaching only) and Kim et al. (US 6,594,377 B1) as applied to claim 1 above, and further in combination with Horiguchi et al. (US 6,490,365 B2).

Regarding claims 2, 3 and 7, while Rice discloses a visual target to align the eye ("a coaxial 'scene' or visual target ... in the visual field" at column 4, line 59; "the location of this visual target will bring the optic disk into the approximate center of the CCD detector" at column 4, line 63),

Rice does not teach an elongated channel having an end into which the user looks and a longitudinal axis at an angle with respect to a centerline of the lens, a light disposed in the channel at a distance from the end into which the user looks where the light is visible when the eye is aligned.

Horiguchi discloses an eye imaging device ("eye image pickup device" at column 1, line 56) comprising an alignment system ("one person can determine the precise direction in which to move one's eye" at column 2, line 5). The alignment system includes an elongated channel (figure 6, numeral 9; "optical fiber cable 9" at column 4, line 61) having an end into which the user looks (figure 6, numeral 11) and a longitudinal axis at an angle with respect to a centerline of the lens (referring to figure 6, the longitudinal axis of numeral 9 is substantially 90 degrees w.r.t. the objective lens axis), a light disposed in the channel at a distance from the end into which the user looks (figure 6, numeral 10; "LED 10" at column 4, line 65) where the light is

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visible when the eye is aligned ("With this setting, when the light shielding portion 3 and the visible guide light 6 are viewed along the light axis 5 from the outside of the mirror barrel 8, they have the same appearance as the annular eclipse shown in FIG. 2(a)" at column 5, line 16).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to incorporate, as the visual target system required by Rice, the elongated channel target system taught by Horiguchi. One would be motivated to do so because the Horiguchi target system is simple (Horiguchi, "simply structured" at column 1, line 55), it can "be mounted in a variety of devices, specifically including portable devices" (Horiguchi, column 1, line 56), and it can facilitate the capture of "precise eye images" (Horiguchi, column 1, line 57), where the owing to the size and location of the marker (i.e. Horiguchi figure 6, numeral 3), the "size of the eye image pickup device is not increased" (Horiguchi, column 2, line 14) and "the marker can be easily recognized visually" (Horiguchi, column 2, line 16).

Regarding claims 5 and 6, looking at Horiguchi's channel 9 in figure 6, the ratio of it's width at the end where it meets LED 10, to it's overall length is approximately 1:12, or 1/14 = .07, thus meeting the claim requirement. Regarding claim 6, 0.7 is "approximately" .04.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rice et al. (US 6,305,804 B1), Hill (US 4,393,366 A – used herein as an inherency teaching only) and Kim et al. (US 6,594,377 B1) as applied to claim 1, and further in combination with Dreher et al. (US 5,303,709 A).

While Rice teaches a lens for focusing a retinal image onto a CCD camera (i.e., figure 1, numerals 11 and 22), Rice does not teach a pinhole lens through which light passes to the capture device.

Dreher discloses a retinal imaging device (figure 7) comprising a pin hole lens (numeral 73) through which light passes to the capture device (numeral 75).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the pinhole lens as taught by Dreher, in order to form the retinal image onto the capture device of Rice, to "eliminate light not returning from the selected focal plane in the eye" (Dreher, column 7, line 30) and so that "stray light reflected from other areas of the focal points is blocked by the pinhole ... cannot reach the [imaging device]" (Dreher, column 5, line 40), thus providing a more accurate image of the retina.

7. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rice et al. (US 6,305,804 B1), Hill (US 4,393,366 A – used herein as an inherency teaching only) and Kim et al. (US 6,594,377 B1) as applied to claim 1, and further in combination with Miller et al. (US 6,690,466 B2).

Rice discloses an illumination source (figure 1, numeral 12), and while Rice states, "the frequency content of this light source is selected dependent upon the compound to be analyzed", where "illumination light may be composed of two (or more) separate lighting systems" at column 4, line 43,

Rice does not teach the specific configuration of the light source, including a red light emitting diode and a green light emitting diode to illuminate the eye.

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Miller discloses an illumination system ("illuminator to illuminate a sample" at column 3, line 40), having use in a retinal imaging system as described in the 102 rejection above, comprising a red light emitting diode and a green light emitting diode that combine to illuminate a sample ("provide light having any desired distribution of wavelengths across a broad range" where "all bands may be on, with precisely chosen amounts of light in each band" at column 3, lines 40-45; "Nineteen LEDs having wavelengths from 420-690 nm …" at column 6, line 33; this spectrum covers the entire visual range, including red and green).

It would have been obvious at the time the invention was made to incorporate, as the illumination system required by Rice (e.g., Rice figure 1, numeral 12, the illumination system taught by Miller as described above. One would be motivated to do so in order to facilitate Rice's selection of frequency content using two or more lighting systems (i.e., "the frequency content of this light source is selected dependent upon the compound to be analyzed", where "illumination light may be composed of two (or more) separate lighting systems" at Rice column 4, line 43) by providing a multitude of light sources (e.g., nineteen LEDs at Miller column 6, line 33) that can provide "any desired distribution" (Miller, column 3, line 42) thus providing Rice with precise and accurate control over the illumination, where any frequency content desired can be achieved. Other benefits and advantages of the Miller system are describe throughout the Miller disclosure, including "simplicity and speed" at column 14, line 22.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rice et al. (US 6,305,804 B1), Hill (US 4,393,366 A – used herein as an inherency teaching only) and Kim et al. (US 6,594,377 B1) as applied to claim 1, and further in combination with Heacock (US 5,861,938 A).

While Rice requires a lens system that includes a "final lens which can be positioned close to ... the cornea" at column 4, line 27,

Rice does not teach specific optical arrangements, including an aspheric surface.

Heacock discloses a retinal imaging system (figures 1 and 2), comprising an aspheric objective lens system (figure 2, numeral 50; "The illumination light as it travels towards the patient's eye 14 is slightly diverging. The weaker surface 52 of the aspheric lens makes the slightly diverging illumination light parallel and directs the illumination light to the stronger surface 54 of the aspheric lens 50. The stronger surface 54 of the aspheric lens focuses the illumination light to a point 56 that is centered on the patient's pupil or generally proximate thereto. The illumination light continues its path until it strikes the retina 58 of the eye 14, thus illuminating an area of the patient's eye within the boundaries of the rays 60 and 62" at column 5, line 35; see Heacock column 6):

$$30 \quad f(Y, A_2, A_4, A_6, C, cc) = A_2Y^2 + A_4Y^4 + A_6Y^6 + CY^2 \left(1 + \sqrt{1 - C^2cc}\right)$$

where A₂, A₄ and A₅ are constants; C represents the curvature of the surface; and co represents the conic constant. For the stronger surface 54 of the lens 50, these values should be within the following ranges:

The aspheric lens 50 of the present invention focuses the illumination light from the illumination system 24 on an area of the patient's eye that is generally proximate to the pupil and the aspheric lens 50 also intercepts light reflected from the patient's eye 14 and focuses the intercepted light onto the image plane 48 that is disposed between the aspheric lens and the eyepiece lens 22. In order to provide such an aspheric lens, each surface 52 and 54 of the lens is preferably described by the polynomial function:

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It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize, as the "final lens system" required by Rice, the aspheric lens taught by Heacock as described above. One would be motivated to do so in order to fulfill Rice's requirement for a lens that can be placed close to the cornea ("final lens which can be positioned close to ... the cornea" at Rice column 4, line 27). That is, Heacock's lens "focuses the illumination light from the illumination system 24 on an area of the patient's eye that is generally proximate to the pupil and the aspheric lens 50 also intercepts light reflected from the patient's eye 14 and focuses the intercepted light onto the image plane 48 that is disposed between the aspheric lens and the eyepiece lens 22" at Heacock column 6, line 20 and as depicted in figures 1 and 2. Thus, the lens of Heacock can be placed close to the cornea and can serve to illuminate the retina and also focus light reflected from the retinal back to the image plane making it a simple, single lens solution to Rice's optical system which also serves to reduce the overall weight of the portable system disclosed by Rice (e.g., Rice figures 3 and 4). One would also be motivated to utilize the Heacock lens because "the aspheric lens 50 produces a 60 degree field of view ... which is extremely wide" at column 6, line 68, where "the real image produced by the aspheric lens 50 is substantially free from distortions" at column 7, line 4.

9. Claims 16, 17, 19, 20, 21, 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rice et al. (US 6,305,804 B1) and Hill (US 4,393,366 A).

Regarding claim 16, Rice discloses a system for capturing an image of a retina of an eye (figures 1, 3 and 4) for identification (not afforded patentable weight: this is an intended use

limitation, not referred back to in the claim body, and not necessary to give life and meaning to the claim) comprising:

a source of illumination light (figure 1, numeral 12);

a lens through which the illumination light passes to illuminate the retina, the lens receiving light reflected from the retina (figure 1, numeral 11; "lenses for projecting illumination light onto the fundus ... and for receiving the light reflected from the fundus" at column 4, line 22);

an image signal generator responsive to light reflected from the retina to generate a signal representing an image of an illuminated area of the retina (figure 1, numeral 22; "the light is reflected from the fundus of the eye 10 ... entering, e.g., a charge coupled device (CCD) detector 22" at column 4, line 47); and

an alignment system to align the eye along an axis that is at a predetermined angle with respect to a centerline of the lens, the angle being selected such that when the eye is aligned along said axis, said centerline intersects an area of the retina other than the fovea (

As described below, Rice teaches a target that is viewed by the fovea whereby an image of the optic disk (which is an area of the eye other than the fovea) is aligned with a centerline of a lens and CCD camera as follows:

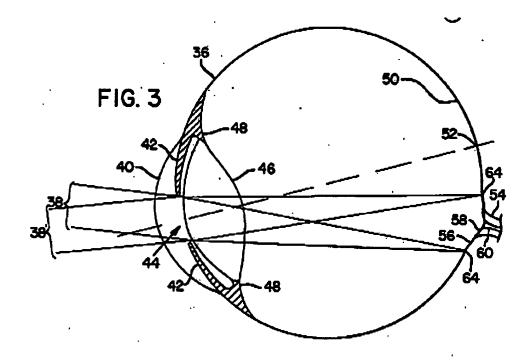
"A coaxial "scene" or visual light target may be included in the visual field of the device so that a patient can fixate his or her eye on this scene" where the "location of this visual target will bring the optic disk into the approximate center of the CCD detector" at column 4, lines 58-

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64; Light in the "visible or infrared range is projected into the eye onto the fundus", and the light reflected back out (e.g., through the pupil) is detected and analyzed, preferably using the area of the optic disk for analyzing the retinal vessels overlaying the optic disk" at column 1, lines 59-65. "measurement of the reflected light from the vessels overlaying the optic disk is preferred" at column 2, line 39

The "fovea" of an eye is the area of sharpest vision. The "optic disk" of an eye is the area where the optic nerve enters the eye, and where there is no vision at all (i.e., the "blind spot"). The fovea and optic disk are separated by an angle of approximately 14 degrees, which is depicted by Figure 3 of the Hill reference, reproduced below, by numerals 52 (fovea) and 56 (optic disk). The Rice system seeks to capture an image of the "optic disk", whereby a visual target is provide to the user which when viewed (i.e., focused on the fovea), projects the optic disk image onto the center of the CCD camera. The CCD camera is centered with the lens as depicted in Rice's figure 1, and as is well known in the art. Thus, given that when the user views the target, the optic disk is centered with the lens and CCD, the target must necessarily be positioned at a predetermined angle with respect to the center of the lens. This is depicted by the Hill reference, as figure 3, as follows:

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In Hill's figure 3, numeral 38' represents a "centering beam" that a user views and which is focused on the fovea 52 as depicted by the dashed centerline. Numeral 38 represents the scanning beam that scans the optic disk 56. It is clear that there is an angle between the centerline of the scanning beam and the centerline of the centering beam.

);

While Rice discloses a visual target disposed at a predetermined angle with respect to the centerline of the objective lens as described above (i.e., the "a coaxial 'scene' or visual target ... in the visual field" at column 4, line 59; "the location of this visual target will bring the optic disk into the approximate center of the CCD detector" at column 4, line 63),

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Rice does not teach the hardware arrangement of the visual target, including an elongated channel having an end into which the user looks and a longitudinal axis at an angle with respect to a centerline of the lens, an object disposed in the channel at a distance from the end into which the user looks where the object is visible when the eye is aligned.

Hill discloses a system for imaging the optic disk ("optic disk" at column 3, line 18), where Hill utilizes the exact same technique as Rice. That is, Hill seeks to image optic disk by having the user view a target on the fovea, whereby the target is at a predetermined angle with respect to the imaging lens (

"FIG. 10 illustrates the relationship between the main or scanner optical axis and the fixation optical axis. The fixation optics are mounted at between 14 and 17 degrees, and preferably at approximately 15.5 degrees from the scanner optical axis or the axis around which the source beam is angularly divergent. Eyeball 36 is oriented so that the image of fixation reticle 84 is focused at fovea 52. Thus, the source beam enters the eye obliquely with the scanner axis intersecting the center of optic disk 56. Lens 92 is oriented to bisect the angle between the fixation axis and the scanner axis so that both beams encounter similar refraction in the lens and reflections from the surfaces of the lens do not create unwanted optical noise."

Hill, column 7, lines 29-42

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Unlike Rice, Hill teaches a hardware arrangement for achieving the optic disk alignment. That is, Hill teaches elongated channel (Figure 1, the channel is depicted as extending from the lens 92, to lens 88 and target 84; this channel is also physically depicted in figure 8 within the context of the entire system) having an end into which the user looks (Figure 8, the user's eye looks into lens 88; also depicted in figure 10) and a longitudinal axis at an angle with respect to a centerline of the imaging lens (the angle between the alignment system having target 84, and the imaging system is clearly depicted in figure 10), an object disposed in the channel at a distance from the end into which the user looks where the object is visible when the eye is aligned (figure 10, target 84 is only visible when the alignment is achieved; see "the eye is indexed relative to a fixation target and positioned both horizontally and vertically to a precise degree" at column 3, line 51).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to incorporate, as the visual target system required by Rice, the elongated channel target system taught by Hill. One would be motivated to do so because:

A. Simplicity: Rice does not teach the hardware details of his alignment system, and Hill teaches a simple hardware construction of an alignment system comprising only three components (i.e., a lens 88, target 84, and light source 86) that aligns the eye in exactly the same manner that is required by Rice; and

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B. Precision: In order that the "eye is indexed relative to a fixation target and

positioned both horizontally and vertically to a precise degree" at column 3, line 51.

Regarding claim 17, Hill's object is a light (figure 10, numeral 86; "light emitting diode

86" at column 5, line 49).

Regarding claim 19, looking at Hill's channel in figure 8, extending from the eye 36, to

lens 88, and then to target 84 and light source 86, the ratio of it's width at the target to it's overall

length is approximately 1:30, or 1/30 = .033, thus meeting the claim requirement.

Regarding claim 21, Hill's channel as depicted in figure 8 (extending from the eye 36, to

lens 88, and then to target 84 and light source 86) is internal to the overall device, which is seal

to external light, and thus the walls are black. The channel itself is generally tubular as depicted

in the figure.

Regarding claim 20, 0.033 is "approximately" .04.

Regarding claim 25, Rice's illumination is non-scanned (e.g. "xenon strobe ... halogen

source" at column 4, line 45).

Regarding claim 29, Rice discloses a CCD camera (figure 1, numeral 22).

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10. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rice et al. (US 6,305,804 B1) and Hill (US 4,393,366 A) as applied to claim 16, and further in combination with Heacock (US 5,861,938 A).

While Rice requires a lens system that includes a "final lens which can be positioned close to ... the cornea" at column 4, line 27,

Rice does not teach specific optical arrangements, including an aspheric surface.

Heacock discloses a retinal imaging system (figures 1 and 2), comprising an aspheric objective lens system (figure 2, numeral 50; "The illumination light as it travels towards the patient's eye 14 is slightly diverging. The weaker surface 52 of the aspheric lens makes the slightly diverging illumination light parallel and directs the illumination light to the stronger surface 54 of the aspheric lens 50. The stronger surface 54 of the aspheric lens focuses the illumination light to a point 56 that is centered on the patient's pupil or generally proximate thereto. The illumination light continues its path until it strikes the retina 58 of the eye 14, thus illuminating an area of the patient's eye within the boundaries of the rays 60 and 62" at column 5, line 35; see Heacock column 6):

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The aspheric lens 50 of the present invention focuses the illumination light from the illumination system 24 on an area of the patient's eye that is generally proximate to the pupil and the aspheric lens 50 also intercepts light reflected from the patient's eye 14 and focuses the intercepted light onto the image plane 48 that is disposed between the aspheric lens and the eyepiece lens 22. In order to provide such an aspheric lens, each surface 52 and 54 of the lens is preferably described by the polynomial function:

where A_2 , A_4 and A_5 are constants; C represents the curvature of the surface; and cc represents the conic constant. For the stronger surface 54 of the lens 50, these values should be within the following ranges:

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize, as the "final lens system" required by Rice, the aspheric lens taught by Heacock as described above. One would be motivated to do so in order to fulfill Rice's requirement for a lens that can be placed close to the cornea ("final lens which can be positioned close to ... the cornea" at Rice column 4, line 27). That is, Heacock's lens "focuses the illumination light from the illumination system 24 on an area of the patient's eye that is generally proximate to the pupil and the aspheric lens 50 also intercepts light reflected from the patient's eye 14 and focuses the intercepted light onto the image plane 48 that is disposed between the aspheric lens and the eyepiece lens 22" at Heacock column 6, line 20 and as depicted in figures 1 and 2. Thus, the lens of Heacock can be placed close to the cornea and can serve to illuminate the retina and also focus light reflected from the retinal back to the image plane making it a simple, single lens solution to Rice's optical system which also serves to reduce the overall weight of the portable system disclosed by Rice (e.g., Rice figures 3 and 4). One would also be motivated to utilize the Heacock lens because "the aspheric lens 50 produces a 60 degree field of view ... which is

extremely wide" at column 6, line 68, where "the real image produced by the aspheric lens 50 is substantially free from distortions" at column 7, line 4.

11. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rice et al. (US 6,305,804 B1) and Hill (US 4,393,366 A) as applied to claim 16, and further in combination with Miller et al. (US 6,690,466 B2).

While Rice states, "the frequency content of this light source is selected dependent upon the compound to be analyzed", where "illumination light may be composed of two (or more) separate lighting systems" at column 4, line 43,

Rice does not teach the specific configuration of the light source, including a red light emitting diode and a green light emitting diode.

Miller discloses an illumination system ("illuminator to illuminate a sample" at column 3, line 40), having use in a retinal imaging system as described in the 102 rejection above, comprising a red light emitting diode and a green light emitting diode that combine to illuminate a sample ("provide light having any desired distribution of wavelengths across a broad range" where "all bands may be on, with precisely chosen amounts of light in each band" at column 3, lines 40-45; "Nineteen LEDs having wavelengths from 420-690 nm …" at column 6, line 33; this spectrum covers the entire visual range, including red and green).

It would have been obvious at the time the invention was made to incorporate, as the illumination system required by Rice (e.g., Rice figure 1, numeral 12, the illumination system taught by Miller as described above. One would be motivated to do so in order to facilitate Rice's selection of frequency content using two or more lighting systems (i.e., "the frequency

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content of this light source is selected dependent upon the compound to be analyzed", where "illumination light may be composed of two (or more) separate lighting systems" at Rice column 4, line 43) by providing a multitude of light sources (e.g., nineteen LEDs at Miller column 6, line 33) that can provide "any desired distribution" (Miller, column 3, line 42) thus providing Rice with precise and accurate control over the illumination, where any frequency content desired can be achieved. Other benefits and advantages of the Miller system are describe throughout the Miller disclosure, including "simplicity and speed" at column 14, line 22.

12. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rice et al. (US 6,305,804 B1) and Hill (US 4,393,366 A) as applied to claim 16, and further in combination with Kim et al. (US 6,594,377 B1).

Rice does not disclose an ultrasonic distance detector, the system being responsive to determine when the eye is a predetermined distance from the image capture device and providing an indication to the user when the eye is at the predetermined distance.

Kim discloses a system for photographing an eye (figures 2-4), comprising an ultrasonic distance transducer ("the distance detector 18 measures a distance by using the infrared light. However, a detector using an ultrasonic wave may be employed" at column 3, line 59), the system being responsive to the transducer to determine when the eye is a predetermined distance from the image capture device ("the distance detector 18 measures a distance between the user and the optical imager, and transmits the measured distance value to the controller 200 through the optical imager driving unit 24. The control unit 200 judges whether the eye of the user is positioned within a predetermined operational range" at column 4, line 33) and providing an

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indication to the user when the eye is at the predetermined distance ("When it is judged that the user is positioned within the operational range, the control unit 200 outputs the control signal to the optical imager 100, thereby automatically enabling the optical imager 100. That is, the camera 10 prepares for capturing the iris image of the user, and simultaneously optical imager driving unit 24 outputs to the outside indicator 22 an active signal informing that the optical imager 100 is enabled" at column 4, line 35).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to incorporate the distance detector of Kim, into the system disclosed by Rice, to judge when the user is in the "operational range" (Kim, column 4, line 33), and then to activate the detector for capturing the image and to output an outside "signal informing that the optical imager 100 is enabled" (Kim, column 4, line 41). One would be motivated to do so by the following factors:

To inform the user of immanent image capture and to therefore remain still;

To properly and accurately adjust the focus mechanism based on the exact distance determined as described by Kim at column 4, line 53 through column 5, line 5 (see "The control unit 200 receives the distance value, computes a zoom-in/zoom-out value and a focus value by using a property table of the camera according to a value corresponding to the distance value, and controls a zoom motor and a focus motor of the camera according to the computed value" and "decides a zoom magnification from the zoom magnification table of the camera according to the previously-set distance by using the distance value between the camera and the iris, transmits the control signal to the camera, and controls the zoom motor of the camera.

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Accordingly, the zoom lens is directly moved, the focus lens is moved to a corresponding position by controlling the focus motor, and thus the focus is directly controlled"), and to increase the focusing speed ("the focusing speed is increased" at Kim, column 5, line 5).

13. Claims 1-3 and 5-15 rejected under 35 U.S.C. 103(a) as being unpatentable over the various combinations of Rice et al. (US 6,305,804 B1) as applied to these same claims above, and further in view of Hill (US 4,393,366 A) as applied to claims 16, 17, 19-23 and 25-29 above. That is, given the combinations of claims 1-3 and 5-15, it would have been obvious at the time the invention was made to one of ordinary skill in the art to incorporate, as the visual target system required by Rice, the elongated channel target system taught by Hill for the same reasons and motivation as cited in the rejection of claim 16 above.

Allowable Subject Matter

- 14. Claims 30-39 are allowed.
- 15. Claims 4, 18 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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16. The following is a statement of reasons for the indication of allowable subject matter: Independent claim 30 and dependent claims 4, 18 and 24, each of which define a retinal image capture system, distinguish over the prior art via. their claimed relationship between an alignment system and a distance detection system. That is, each recite an alignment system comprising an angled channel having a distal light source with first and second states, where the user looking into the channel is in proper alignment when the light is visible, and a distance detector that determines when the eye is within a predetermined distance from the capture system, where the light in the alignment system changes state when the eye is at the predetermined distance. That is, "the single LED 70 provides an indication to the user that the eye 20 is correctly aligned along the longitudinal axis 34 and is at a desired distance from the system 10" at applicant's specification page 13, line 25. This ensures that the user is notified when the proper distance (i.e., z-axis alignment) is achieved in a non-disruptive manner via. the same light source used for the x and y axis alignment. There is no suggestion in any of the above references and without improper hindsight for this combination of elements.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian P. Werner whose telephone number is 571-272-7401. The examiner can normally be reached on M-F, 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew C. Bella can be reached on (571) 272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Brian Werner Primary Examiner Art Unit 2624 June 29, 2006

BRIAN WERNER
PRIMARY EXAMINER